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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,016	KIM ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 October 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/17/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-7 and 9 and the election of *Bifidobacterium* as Specie A from Claim 4 in the reply filed on 17 October 2006 is acknowledged.

Claims 1, 2, 4 and 5 are currently pending.

Claims 1, 2, 4 and 5 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 17 February 2006 was filed after the mailing date of the original claims, specification, abstract and oath/declaration on 8 October 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because the x-axis is not properly labeled and it is unclear as to what subject matter Applicant is describing in the drawings. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to for the following reasons: The abstract recites, "The present invention relates to the novel use of processed ginseng extract and the saponin compounds isolated therefrom for preventing and treating brain stroke and brain diseases in a human or mammal. More particularly, the present invention relates to the novel use of processed ginseng product with enhanced pharmacological effects due to serial treatment, i.e. acid-treatment and subsequent bio-converting treatment, such as lactic fermenting and intestinal-bacterial fermenting process". It is suggested that the terms "present invention" and "novel" be deleted from

the language of the abstract. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of "present invention" and "novel" into the language of the abstract is not appropriate. Furthermore, Applicant should amend the specification by removing the words preventing and treating brain stroke and brain diseases and instead insert what Applicant is enabled for (See rejection under 112 1st paragraph, below). Please also correct the grammar in the abstract. There several punctuation errors that occur within the Abstract that must be corrected. Appropriate correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: Please note that the following is just one example of the language that should be changed. The entire specification should be rewritten because there are numerous terms and phrases that are generally narrative and indefinite, failing to conform with current U.S. practice. The following is just one example of the language that is included in the specification that should be changed: "Brain stroke is consisted of two type, i.e., ischemic stroke occurred from ischemic condition of brain tissue caused by intervention or decrease of blood supply to brain and hemorrhagic stroke occurred from the bleeding of brain blood vessel where the former occupy about 80% among total patient suffered from brain stroke" on page 1, lines 18-21. In fact, the entire specification is ambiguous, as previously mentioned, and contain relative terms, wherein the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the

art would not be reasonably apprised of the scope of the invention, and because these lines are generally narrative and indefinite, failing to conform with current U.S. practice. The entire specification appears to be a literal translation into English from a foreign document and is replete with grammatical and idiomatic errors.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: A method of preparing a pharmaceutical composition comprising fermented ginseng.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1, which reads, "for the treating and preventing human or mammal suffering from brain strokes and brain diseases" in lines 3-5, should be corrected to read for the treatment or prevention of brain strokes and brain diseases in a human or mammal. Please note that claim 1 bas been rejected under 35 U.S.C. 112, first paragraph and that the claim should be amended to reflect what Applicant is actually enabled for. This proposed correction is merely to illustrate an appropriate way to phrase the current claim, but is in no way meant to indicate that Applicant's claim should continue to read in this way, since, as mentioned before and as shown below, Applicant is not enabled for this broad language. Furthermore, the article, an should be inserted in line 5 between "with" and

"lactic solution" and "lactic-acid bacteria" should be changed to lactic acid bacteria in line 6. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: please insert strain between "lactic acid bacteria" and "comprises" in lines 1 and 2 and insert of strains between "mixture" and "thereof" in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.O1(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to a method of preparing a pharmaceutical composition comprising processed ginseng extract, as an active ingredient, in an effective amount, together with a pharmaceutically acceptable carrier, for the treating and preventing human or mammal suffering from brain strokes and brain diseases, wherein the method comprises the steps of treating ginseng with acid solution and subsequent fermentation with lactic-acid bacteria.

Breadth of the Claims: The claims are broad in that a therapeutically effective amount of a therapeutically effective amount of any type of processed ginseng extracts from any or all types of ginseng may be administered to treat or prevent human or mammal suffering from any type of brain strokes and any type of brain diseases. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes a method of testing various concentrations of test samples of non-processed ginseng and acid-processed ginseng, wherein the ginseng extracts tested were extracted in the following manners: *Panax ginseng* root was dissolved in water, extracted with butanol and concentrated to obtain a butanol fraction, then incubated with *Bifidobacterum* KK-2 and extracted with butanol, concentrated and dried to obtain processed ginseng extract; *Panax ginseng* root was combined with distilled water containing 0.1% lactic acid, incubated and extracted with butanol to provide a processed ginseng extract; *Panax ginseng* was extract with methanol, concentrated, dissolved in water, extracted with butanol, concentrated, subjected to silica gel column

chromatography to isolate a saponin fraction; *Panax ginseng* was extracted with methanol, concentrated, dissolved in distilled water, extracted with butanol, subjected to silica gel chromatography to isolate a saponin fraction, which was then incubated with *Bifidobacterum* KK-2, wherein the incubates were extracted with butanol, concentrated and dried to obtain processed ginseng extract, by administering various concentrations of the test samples to ischemic brain animal model.

The specification envisions that any and all types of processed ginseng extracts from any or all types of ginseng will have utility in humans in treating or preventing brain strokes and any type of brain diseases.

However, no working examples are provided with regard to a method preventing brain strokes nor are there any working examples provided with regard to a method for treating or preventing any or all types of brain diseases. Furthermore, no working examples are provided that demonstrate the efficacy of all types of processed ginseng extracts from any or all types of ginseng in treating or preventing brain strokes nor are there any working examples provided that demonstrate the efficacy of all types of processed ginseng extracts in preventing or treating any or all types of brain diseases.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, Zhang et al. (See reference U) teach a method of studying the influences of ginenosides Rb1 and Rg1 (active components of the total saponins of *Panax ginseng*) on rat brains against ischemia-reperfusion injury, wherein rat focal cerebral ischemia was induced by reversible middle cerebral artery occlusion without craniectomy. Zhang further teaches

that the influences of ginsenoside Rb1 and Rg1 on infarct size, neurologic deficit and the contents of calcium and potassium in the infarct were observed and that in a 2 hour ischemia, Rb1 10-40 mg.kg-1 i.v. 30 min before middle cerebral artery occlusion decreased IS by 20%-49% and ND score from 5.1 to 4.1-2.3, and inhibited calcium accumulation and potassium loss by 22%-50% and 18-37%, respectively; Rb1 10-40 mg.kg-1 i.v. immediately after MCA was recanalized decreased infarct size by 12%-35% and neurologic deficit score from 5.2 to 4.3-3.3, and inhibited Ca accumulation and K loss by 10%-40% and 17%-30%, respectively, and in permanent ischemia, Rb1 40 mg.kg-1 i.v. reduced infarct size, neurologic deficit, calcium accumulation and potassium loss. However, Rg1 40 mg.kg-1 i.v. did not show effect on both permanent and 2-h middle cerebral ischemia.

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a method comprising the administration of any type of processed ginseng extracts from any or all types of ginseng to treat or prevent human or mammal suffering from any type of brain strokes and any type of brain diseases. The Office further notes that while the specification discloses that the claim-designated methods and claim designated compositions will have utility in humans in treating or preventing any type of brain strokes and any type of brain diseases, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of compositions comprising any type of processed ginseng extracts from any or all types of ginseng to any subject. Furthermore, the specification is vague in that it does not disclose what "mammals" were involved in the study. It is impossible to

tell what types of animals that Applicant used in determining and studying the activity of certain extracts of ginseng on brain activity.

It should be noted that at the time of filing of the present application, the art of medicine did not recognize the administration of any type of processed ginseng extracts from any or all types of ginseng for the treatment or prevention of any type of brain strokes and any type of brain diseases comprising the step of administering any type of processed ginseng extracts from any or all types of ginseng to treat or prevent brain strokes and any type of brain diseases in humans.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to make and use any type of processed ginseng extracts from any or all types of ginseng in the treatment or prevention of any or all types of ginseng to treat or prevent brain strokes and any type of brain diseases in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify processed ginseng extracts that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 1, 2, 4 and 5 are not considered to be fully enabled by the instant specification.

Claim 5 is rejected under USC 112, first paragraph because the claimed invention is not deemed enabled without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological material.

It is apparent that the microorganism(s) is/are required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it/they is/are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. 1.802.

The specification does not provide a repeatable process for obtaining the bacterial strains, *Bifidobacterium* K-103, *Bifidobacterium* K-506, *Bifidobacterium* K-513, *Bifidobacterium* K-525, *Bifidobacterium* KK-1 and *Bifidobacterium* KK-2, and it is not apparent if *Bifidobacterium* K-103, *Bifidobacterium* K-506, *Bifidobacterium* K-513, *Bifidobacterium* K-525, *Bifidobacterium* KK-1 and *Bifidobacterium* KK-2 are readily available to the public. The specification must contain the date that the bacterium/bacteria was/were deposited, the name of the bacterium/bacteria and the address of where the bacterium/bacteria was/were deposited.

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain(s)

has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 C.F.R. 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. 1.809 (d) should be added to the specification. See 37 C.F.R. 1.803-1.809 for additional explanation of

these requirements.

Please note that waving the biological deposit requirement requires fulfillment of one of two-prong conditions: (a) the strain is readily known and available or (b) the strain can be made or isolated without undue experimentation. (See, e.g, 37 CFR 1.802 and MPEP 2404.01-02) The Office will accept commercial availability as evidence that a biological material is known and readily available *only when the evidence is clear and convincing that the public has access to the material* (See MPEP 2404.01). The instant record is unclear in regards to whether the claimed *Bifidobacterium* K-103, *Bifidobacterium* K-513, *Bifidobacterium* K-525, *Bifidobacterium* KK-1 and *Bifidobacterium* KK-2 was readily known or available and/or that it could be isolated without undue experimentation. In fact, the strains *Bifidobacterium* K-103, *Bifidobacterium* K-513, *Bifidobacterium* K-525, *Bifidobacterium* KK-1 and *Bifidobacterium* KK-2 do not appear anywhere within the texts of the evidence provided by Applicant. Likewise Examiner's search of the patent and non-patent literature did not retrieve any sources citing these particular strains of bacteria. Therefore, it is the position of the Office that the bacterial strains instantly claimed cannot clearly and unequivocally be readily known since the evidence provided by Applicant is not clear and convincing that the public has access to the material.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethanopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical as noted in this application. The common name or traditional/ethanopharmacological name may have several different Latin names referring to various genus-species of the plant and it is unclear as to which genus and species Applicant is referring. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Applicant may overcome the rejection by placing the genus-species name of "ginseng" in parentheses after the term "ginseng".

The metes and bounds of Claim 1 are rendered uncertain by the phrase "A method of preparing a pharmaceutical composition comprising processed ginseng extract" because it is unclear as to what type of extract Applicant is claiming. Is Applicant claiming an aqueous extract, an organic extract or is Applicant claiming a specific compound extracted from ginseng? Furthermore, the term "processed" is not understood. When an extract is made, clearly the plant must be processed to obtain an extract. The term "processed" is a relative term which renders the claim indefinite. The

term "processed" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 2 recites the limitation "wherein said ginseng" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "the mixture" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al. (N, JP 63-216432 A, Translation provided herein), in view of Tsuji et al. (O, JP 2001-112437 A, Translation provided herein), Bae et al. (V), Roberfroid (W), Chin et al. (P, JP 07-089863 A, Partial translation provided herein), Hikino et al. (Q, JP 61-115013 A, Partial translation provided herein), Hashimoto et al. (R, JP 03-277247 A, Translation provided herein) and http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm (X).

Ishida teaches a method of making a yogurt containing medicinal ginseng wherein the ginseng (roots, natural products or tissue cultured products) is medicinal ginseng, such as *Panax ginseng*, *Panax japonicus* C. A. Meyer, *Panax quinquefollum* L., *Panax notoginseng* (Burk) F. H. Chen and *Eleutherococcus senticosus* (See pages 2 and 3) and wherein the yogurt is obtained by admixing lactic bacteria to cow milk or ewe milk, maintaining the temperature of the mixture at between 35 and 45 °C in an anaerobic condition, and fermenting the mixture for about 24 hours (See page 4). Ishida further teaches that the medicinal ginseng yogurt is made by combining the medicinal ginseng, which is made by mixing a dried article of medicinal ginseng or ginseng calluses in water for 24 hours, then combing the natural medicinal ginseng with water, mixing the mixture to provide a liquid, which was filtered, to obtain medicinal ginseng (See pages 6 and 7). Ishida further teaches that the medicinal ginseng is

inoculated with lactic acid bacteria and left to ferment for 25 hours at a temperature of 35 °C (See pages 7 and 8).

Tsuji teaches a method of making yogurt by combining milk with Bifidobacterium, such as *Bifidobacterium bifidum* and *Bifidobacterium infantis* (See page 3, paragraphs 0016-0018 and page 4, paragraph 0021) or *Lactobacillis*, which are both types of lactic acid bacteria, wherein the pH is generally between 4.0 and 7.0 and that the temperature at which the cultures are grown are at 30-39 °C (See page 2, paragraphs 0010). Tsuji further teaches that it is necessary to perform the process of making yogurt at a temperature of between 30 and 42 °C and by adding an acid (See page 2, paragraph 0014) to reduce the pH to 4-5.5 (See page 3, paragraph 0018, continued onto page 4).

Bae teaches that ginsenosides, which are extracted from ginseng, are added to Bifidobacterium K-506 and incubated (See columns 1 and 2, page 743). Bae further teaches that the incubation increases the pharmacologic activity of the compounds.

Roberfroid teaches that probiotics are viable microbial dietary supplement that beneficially affects the host through its effects in the intestinal tract and are widely used to prepare fermented dairy products such as yogurt or freeze-dried cultures. Roberfroid further teaches that the bacterial genera most often used as probiotics are lactobacilli and bifidobacteria and that after passage through the stomach and the small intestine, some probiotics survive and become established transiently in the large bowel. Indeed, the colon's fermentation capacity may be modified after probiotic intake, and oral intake of certain lactic acid bacteria will increase the number of lactobacilli or bifidobacteria in human feces (See page S1682S).

Morishita teaches a method of extracting medicinal plants using methanol, aqueous ethanol or water, wherein the medicinal plants are roots, leaves, buds and fruit of ginseng, which may be purified and formulated into tables, granules and capsules of oral administration.

Hashimoto teaches a method of making a food comprising ginseng inoculated with lactobacillus, which is a type of lactic acid bacteria, at a pH of 4.0 or higher (See page 4), wherein an extract of ginseng may be made from the stems of Siberian ginseng, roots of other ginsengs, such as Asian ginseng, American ginseng, or tissue cultures from Asian ginseng, American ginseng, Siberian ginseng, *Panax japonicas*, or *Panax notoginseng* (See pages 4 and 5). Hikino teaches a cosmetic containing a polysaccharide obtained from ginseng, which reads on an extract of ginseng, obtained *Panax ginseng*, *Panax japonicus* C. A. Meyer, *Panax quinquefollum* L. or *Panax notoginseng* having a skin-activating effect and suitable for promotion of beauty and health of the skin.

http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm teaches that yogurt may be used as a soothing ointment for sunburn, as a cosmetic mask and that yogurt is beneficial to the skin.

The teachings of Ishida, Tsuji, Bae, Roberfroid, Morishita, Hikino, Hashimoto and http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm are set forth above. Ishida does not teach a method of preparing a pharmaceutical composition comprising the step of treating

ginseng with acid solution, nor does Ishida teach that ginseng comprises the stem, petal, leaf or fruit, nor does Ishida teach using Bifidobacterium, such as *Bifidobacterium bifidum*, *Bifidobacterium infantis* and other strains of lactic acid bacteria, such as *Bifidobacterium* K-506. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method taught by Ishida to make a pharmaceutical composition because at the time the invention was made, a method of making a composition containing medicinal ginseng wherein the ginseng (roots, natural products or tissue cultured products) is medicinal ginseng, such as *Panax ginseng*, *Panax japonicus* C. A. Meyer, *Panax quinquefollum* L., *Panax notoginseng* (Burk) F. H. Chen and *Eleutherococcus senticosus* and wherein the yogurt is obtained by admixing lactic bacteria to cow milk or ewe milk, maintaining the temperature of the mixture at between 35 and 45 °C in an anaerobic condition, and fermenting the mixture for about 24 and that the medicinal ginseng yogurt is made by combining the medicinal ginseng, which is made by mixing a dried article of medicinal ginseng or ginseng calluses in water for 24 hours, then combing the natural medicinal ginseng with water, mixing the mixture to provide a liquid, which was filtered, to obtain medicinal ginseng and that the medicinal ginseng is inoculated with lactic acid bacteria and left to ferment for 25 hours at a temperature of 35 °C was known, as clearly taught by Ishida, as was a method of making yogurt by combining milk with Bifidobacterium, such as *Bifidobacterium bifidum* and *Bifidobacterium infantis* or *Lactobacillis*, wherein the pH is generally between 4.0 and 7.0, that the temperature at which the cultures are grown are at 30-39 °C and that it

is necessary to perform the process of making yogurt at a temperature of between 30 and 42 °C and by adding an acid to reduce the pH to 4-5.5, as clearly taught by Tsuji, as was that ginsenosides, which are extracted from ginseng, are added to *Bifidobacterium* K-506 and incubated and that the incubation increases the pharmacologic activity of the compounds, as clearly taught by Bae, as was that probiotics are viable microbial dietary supplement that beneficially affects the host through its effects in the intestinal tract and are widely used to prepare fermented dairy products such as yogurt or freeze-dried cultures, that the bacterial genera most often used as probiotics are lactobacilli and bifidobacteria and that after passage through the stomach and the small intestine, some probiotics survive and become established transiently in the large bowel, that the colon's fermentation capacity may be modified after probiotic intake, and oral intake of certain lactic acid bacteria will increase the number of lactobacilli or bifidobacteria in human feces, as clearly taught by Roberfroid, as was a method of extracting medicinal plants using methanol, aqueous ethanol or water, wherein the medicinal plants are roots, leaves, buds and fruit of ginseng, which may be purified and formulated into tables, granules and capsules of oral administration, as clearly taught by Morishita, as was a method of making a food comprising ginseng inoculated with lactobacillus, which is a type of lactic bacteria, at a pH of 4.0 or higher, wherein an extract of ginseng may be made from the stems of Siberian ginseng, roots of other ginsengs, such as Asian ginseng, American ginseng, or tissue cultures from Asian ginseng, American ginseng, Siberian ginseng, *Panax japonicas*, or *Panax notoginseng*), as clearly taught by Hashimoto, as was a cosmetic

containing a polysaccharide obtained from ginseng, which reads on an extract of ginseng, obtained *Panax ginseng*, *Panax japonicus* C. A. Meyer, *Panax quinquefollum* L. or *Panax notoginseng* having a skin-activating effect and suitable for promotion of beauty and health of the skin, as clearly taught by Hikino, as was that yogurt may be used as a soothing ointment for sunburn, as a cosmetic mask and that yogurt is beneficial to the skin, as clearly taught by http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm. Therefore, it would have been obvious to make a pharmaceutical composition, such as yogurt (which is known to have beneficial skin effects when applied to the skin and also is ingestible and when ingested is also beneficial to health), comprising processed ginseng as an active ingredient in an effective amount, wherein the parts of ginseng used are the root, stem, petal, leaf, fruit or tissue culture, wherein the ginseng is combined with a pharmaceutically acceptable carrier, such as water, and wherein the method comprises the steps of treating ginseng with acid solution and subsequently fermenting the solution with lactic acid bacteria, such as *Bifidobacterium*, wherein the Bifidobacterium is *Bifidobacterium infantis*, *Bifidobacterium bifidum*, or *Bifidobacterium* K-506 by combining the teachings of Ishida, Tsuji, Bae, Roberfroid, Morishita, Hikino, Hashimoto and http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm.

It is noted that the references do not teach that the composition can be used for treating or preventing human or mammal suffering from brain strokes or brain diseases,

as is instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Please also note that the order of the method steps do not matter provided that the final product as disclosed in the art is the same as that claimed by Applicant. (See MPEP § 2111.01(I)).

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court

explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that plant parts and extracts of ginseng and that yogurt, which can be made by using lactic acid bacteria, such as *Bifidobacterium*, as effective ingredients in compositions for treating skin, it would have been obvious to combine these plants with the expectation that such a combination would be effective in pharmaceutical, such as pharmaceutical skin care compositions. Thus, combining them flows logically from their having been individually taught in prior art.

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a type of lactic acid bacteria, to pick and choose the acidity of a solution and to pick and choose essential method steps to provide a method for making a pharmaceutical composition comprising ginseng extract as an active ingredient, wherein the ginseng extract is combined with a pharmaceutically acceptable carrier, treating the solution with an acid solution and fermenting the solution with lactic acid bacteria, wherein the lactic acid bacteria may be any type of *Bifidobacterium* and wherein it would have been obvious to use *Bifidobacterium* naturally occurring the gut, such as *Bifidobacterium* K-506, because *Bifidobacterium* are viable microbial dietary supplement that beneficially affects the host through its effects in the intestinal tract and are widely used to prepare fermented dairy products such as yogurt or freeze-dried cultures, that the bacterial genera most often

used as probiotics are lactobacilli and bifidobacteria and that after passage through the stomach and the small intestine, some probiotics survive and become established transiently in the large bowel and that gut *Bifidobacterium*, such as *Bifidobacterium* K-506, may be incubated with ginseng extract. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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